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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

GREGORIA GRIJALVA, *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF AMICUS CURIAE AMERICAN ASSOCIATION OF HEALTH PLANS IN SUPPORT OF PETITIONER

JEFFREY W. KING
(Counsel of Record)
CHRISTOPHER FLYNN
KING, PAGANO & HARRISON
1730 Pennsylvania Ave., N.W.
Suite 900
Washington, D.C. 20006
(202) 371-6800
Counsel for Amicus Curiae.

Washington, D.C. • THIEL PRESS • (202) 328-3288

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INTEREST OF THE AMICUS

Amicus curiae respectfully submits this brief in the support of Petitioner. Amicus curiae, the American Association of Health Plans, Inc. ("AAHP"), is a non-profit trade association representing approximately 1,000 managed care companies, many of whom are currently involved in the Medicare program throughout the United States. AAHP's principal purpose as a trade association is to foster, encourage and assist development of an organized, pre-paid healthcare system as an alternative to other arrangements for the delivery of healthcare services. AAHP's brief focuses on two of the questions presented: Issue 1 (whether the denial by private health maintenance organizations ("HMOs") of healthcare services under the Medicare Program constitutes government action) and Issue 3 (whether the Court should vacate the judgments below in light of the new legislation and regulations governing Medicare). AAHP also addresses the impact that the decision below will have if the Court does not vacate it.[1]

By participating in this action, AAHP seeks to protect its members' rights. AAHP is concerned that, if the lower court judgments in this case are upheld, the imposition of "government actor" status on private healthcare companies could have a far-reaching impact on all managed care organizations who participate in publicly-funded programs. The judgments will impose costly administrative requirements on Medicare HMOs in all aspects of their operations. In addition, as a result of the broad

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[1] Pursuant to Supreme Court Rule 37.6, AAHP states that no counsel for a party authorized this brief in whole or part; and that no person or entity, other than the amicus and its counsel, contributed monetarily to the presentation or submission of this brief. The consents to the filing of this amicus brief in this proceeding have been filed with the Clerk.

application of the government action doctrine by the courts below, the decisions in this case are likely to be the basis of even more attenuated claims of government action in the future. Indeed, at least one Medicaid healthcare provider has already cited the district court's decision as a basis for challenging the non-renewal of contracts. The decisions will also inevitably expand the grounds for beneficiary litigation challenging medical decisions, benefit changes, coverage determinations and review procedures.

In addition, the court of appeals' decision will likely have an adverse impact on the new "Medicare+Choice" program and Medicare beneficiaries. The expansive application of the government action doctrine to private healthcare companies will discourage participation in the Medicare+Choice program by health plans and their affiliated providers.

STATEMENT OF CASE

This action involves the coverage of medical care by HMOs under the Medicare program. Respondents sought declaratory and injunctive relief against Petitioner, the Secretary of the Department of Health and Human Services ("the Secretary"), for allegedly failing "to enforce due process requirements," and "to monitor HMO denials of medical services to enrolled Medicare beneficiaries." *Grijalva v. Shalala*, 152 F.3d 1115, 1117 (9th Cir. 1998).

At the time of the district court litigation, HMOs participated in the Medicare program under "risk-sharing" agreements pursuant to 42 U.S.C. §1395mm(g). Congress has since abolished that program and replaced it with the new Medicare+Choice program. Under the former risk contracts, HMOs were paid a fixed monthly

payment for each Medicare beneficiary who chose to enroll in the HMO. The fixed monthly premium rates were based, in large part, on the fee-for-service costs necessary to provide the basic Medicare benefits. Risk-sharing HMOs were also required to submit an "adjusted community rate" ("ACR") to the Secretary each year. The ACR represents the amount the HMO would charge in the open market for a package of basic Medicare benefits. 42 U.S.C. §1395mm(e)(3). If the ACR for the basic Medicare benefits was below the monthly rate, an HMO could either refund the difference to the government or provide "additional benefits" to beneficiaries valued at the difference between the HMO's ACR and the Medicare premium. 42 U.S.C. §1395mm(g)(2).[2] Traditionally, HMOs added benefits and reduced or eliminated any co-payment due from the beneficiary. Accordingly, Medicare risk-sharing HMOs generally provided beneficiaries with the basic Medicare benefits under the statute plus additional benefits at no additional charge to the government or the beneficiary.

The Secretary did not adjust monthly payments based on the services actually utilized by beneficiaries. Rather, the risk-sharing Medicare HMOs bore the risk that increased patient needs and attendant costs could exceed the fixed monthly payments received for each Medicare beneficiary. These risk-sharing components of the Medicare contracts were similar to HMO coverage purchased by individuals or employers for their employees in the commercial market.

Respondents below alleged that Petitioner failed to enforce adequately her statutory and due process obliga-

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[2] Under the risk-sharing contracts, HMOs were also permitted to provide additional benefits for a premium charged to Medicare enrollees subject to the express approval of the Health Care Financing Administration ("HCFA"). *Id.* at §1395mm(c)(2).

tions under the Medicare statute and regulations when HMOs denied coverage for claims submitted by Medicare beneficiaries. The district court held that Respondents' "claim hinge[d] on whether HMO denials of service constitute[d] state action." *Grijalva v. Shalala*, 946 F. Supp. 747, 751 (D. Az. 1996). Finding state action, the district court granted Respondents' motion for summary judgment, ruling that the notices of denial of coverage were difficult to understand. The court issued an injunction specifying the type of written notice required for coverage denials and the time requirements necessary to comport with the due process mandates of the Fifth Amendment. The injunction also mandated that the Secretary monitor and investigate compliance with the court's notice requirements, and barred the Secretary from renewing contracts with any HMO that did not comply with the provisions of the court's order. The Court of Appeals for the Ninth Circuit upheld the district court's decision, relying heavily on the district court's reasoning.

On August 5, 1997, while the appeal was pending, Congress passed the Balanced Budget Act of 1997 ("BBA"), Pub. L. No. 105-33, Sec. 4001-4002, 111 Stat. 275-330. The BBA eliminated all risk-sharing contracts and thereby effectively repealed Section 1395mm(g), the statutory provision at issue in this case. Congress replaced risk-sharing contracts with the Medicare+Choice program. The BBA also eliminated the Secretary's authority to renew risk-sharing contracts as of January 1, 1999. Pursuant to the new law, the Secretary promulgated regulations to implement the new Medicare+Choice program.

Petitioner filed her Writ for Petition of Certiorari on February 11, 1999. Petitioner requested that the Court hold the Petition until the Court issued its opinion in

American Manufacturers Mutual Insurance Co., et al. v. Sullivan, et al., 526 U.S. ____, No. 97-2000, (March 3, 1999) (slip op.). Now that the Court has issued its ruling in *Sullivan*, the Court should grant Petitioner's writ. The Court should vacate the court of appeals' decision, direct the court of appeals to vacate the district court's injunction, and remand the case to the district court for consideration of the Respondents' claims in light of the *Sullivan* decision, the passage of the BBA and the regulations promulgated thereunder.

SUMMARY OF ARGUMENT

1. The Court Of Appeals' Ruling Is Inconsistent With The *Sullivan* Decision

This Court's recent opinion in *Sullivan* rejected the very factors that the lower courts in the instant case employed to evaluate potential government action, including "joint participation" in a program and extensive government regulation. *Sullivan*, slip op., at 16. Moreover, as this Court reaffirmed in *Sullivan*, private decisions regarding medical benefits, as are at issue here, are not the type of action traditionally taken by the government. Rather, such action is traditionally "made by concededly private parties, and 'turns on . . . judgments made by private parties' without 'standards established by the State.' " *Sullivan*, slip op., at 11 (quoting *Blum v. Yaretsky*, 457 U.S. 991, 1008 (1982)). Accordingly, the court of appeals decision below, finding that an HMO assumes the role of a government actor when it denies coverage of a medical benefit for a Medicare beneficiary, runs afoul of this Court's decision in *Sullivan*.

2. HMO Actions That Violate The Medicare Statute Do Not Constitute Government Action

Respondents contend below that the HMOs' written coverage determinations did not provide the procedural safeguards mandated by the Medicare statute and regulations, and that the Secretary failed to enforce those safeguards. The courts have previously held that actions by a private party in violation of statutory authority or administrative regulations do not constitute government action. *Starnes v. Capital Cities Media, Inc.*, 39 F.3d 1394, 1397 (7th Cir. 1994) (citing *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 937 (1982)). As this authority demonstrates, the HMO coverage decisions at issue do not constitute government action to the extent that HMOs acted outside of the statutory and regulatory requirements imposed by the Medicare Act.

3. The Decisions Will Have Unfavorable And Far-reaching Effects

If the court of appeals' holding in this case is permitted to stand, serious adverse consequences will result. If the requirements for participation in the Medicare+Choice program are to be dictated, in part, by the application of the government action doctrine by individual courts on an *ad hoc* basis, many HMOs will be discouraged from participating or from continuing to participate in such an unsettled regulatory environment.

The decision below also is likely to spawn litigation by providers as well as beneficiaries. Providers already have argued, based on the decisions below, that HMOs act as the government's proxy when choosing the providers with whom they wish to contract for purposes of Medicaid. *Catanzano v. Wing*, 103 F.3d 223, 227 (2d Cir. 1996).

That case demonstrates the breadth of the decisions below and the seemingly limitless application of those decisions unless they are vacated.

4. The Balanced Budget Act Of 1997 Mandates The Case Be Vacated And Remanded

In August 1997, Congress passed the Balanced Budget Act ("BBA"). This Act abolished "risk-sharing" HMOs in the Medicare Program as of January 1, 1999. Moreover, the BBA established enhanced notice and appeal opportunities to beneficiaries under the Medicare+Choice program. As a result, the court of appeals based its decision on a program that no longer exists. The BBA's abolishment of the statutory basis for the district court and the court of appeals' decisions mandates that this case be remanded to consider the BBA and the Secretary's new regulations.

REASONS FOR GRANTING THE PETITION

I.

THE COURT OF APPEALS' RULING SHOULD BE VACATED IN LIGHT OF THIS COURT'S RECENT RULING IN THE *SULLIVAN* CASE.

The lower courts' decisions are at odds with the opinion issued by this Court on March 3, 1999, in *American Manufacturers Mutual Insurance Company, et al. v. Sullivan*, 526 U.S. ___ , No. 97-2000 (March 3, 1999) (slip op.). In *Sullivan*, this Court rejected the Third Circuit's application of the state action doctrine to private insurers seeking utilization review of treatment requests for individuals receiving workers' compensation benefits. That ruling is controlling over the instant case and calls for the Court to vacate the court of appeals' decision here.

The issues in both cases are nearly identical. In *Sullivan*, the Court considered "whether a *private insurer's* decision to withhold payment for disputed medical treatment may be fairly attributable to the State so as to subject insurers to the constraints of the Fourteenth Amendment." *Sullivan*, slip op., at 10 (emphasis in original). Similarly, in the instant case, one of the issues before the Court is:

> [w]hether the decision by a Section 1395mm(g) HMO to deny an enrolled Medicare beneficiary's request for health services constitutes government action subject to the requirements of the Due Process Clause of the Fifth Amendment.

Pet. Br. at I. Both cases turn on whether health benefits coverage determinations by private entities, in one case workers' compensation insurers and in the other Medicare HMOs, constitute government action. The Court in *Sullivan* answered this question "no." *Sullivan*, slip op., at 10.

The courts below failed to apply the appropriate standards for analyzing claims of government action by private entities. In a series of decisions over the past thirty years, this Court has established the proper analytical framework and standards to determine whether it is appropriate to impose on federal and state officials responsibility for the conduct of private parties. The benchmarks for establishing government action are not easily met in order to protect private citizens' actions against the unfair imposition of constitutional restraints, and to avoid "imposing on the states, its agencies or officials, responsibility for conduct which they cannot fairly be blamed." *Lugar*, 457 U.S. at 936-937.

As recently reaffirmed in *Sullivan*, this Court established two prerequisites for imposing due process requirements on private entities acting as a proxy for the

government. First, the challenged activity must be "caused by the exercise of some right or privilege created by the State or by a rule of conduct imposed by the [government] or by a person for whom the [government] is responsible." *Sullivan*, slip op., at 8 (quoting *Lugar*, 457 U.S. at 937); *also see*, *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149, 156 (1978). Second, "the party charged with deprivation must be the person who may fairly be said to be a [government] actor." *Ibid.* In the case before the Court, the Medicare statute established the rights at issue. Accordingly, Respondents likely satisfy the first prong of the test to determine government action. Respondents fail, however, to fulfill the second prong—identifying a party that is acting as a proxy for the federal government.

The court of appeals based its finding of government action on the contention that risk-sharing HMOs and the Secretary "jointly participated" in the Medicare program. *Grijalva*, 152 F.3d at 1119-1120. The court of appeals' reliance on the "joint participation" theory is misplaced. In *Sullivan*, this Court reversed a Third Circuit decision that relied on the same joint participation theory as relied upon by the court of appeals in the instant case. The Third Circuit ruled that the Pennsylvania workers' compensation system "inextricably entangles the insurance companies in a partnership with the Commonwealth such that they become an integral part of the state in administering the statutory scheme." *Sullivan v. Barnett*, 139 F.3d 158, 170 (3d Cir. 1998), *rev'd*, 526 U.S. ___ (1999). The *Sullivan* Court rejected "joint participation" between insurance companies and the State as a basis for establishing government action. *Sullivan*, slip op., at 16-17.

The mere invocation of "joint participation" is insufficient to establish government action. Rather, the courts

must assess the facts and the specific allegations made by the plaintiff that give rise to the claim. *Ibid.* The courts determine whether the government "has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the State." *Id.*, slip op., at 10 (quoting *Blum*, 457 U.S. at 1004). This Court recognizes that action taken with "mere approval or acquiescence" of the government is not sufficient to create government action. *Ibid.*

The court of appeals below identified five facts in support of its finding of joint participation between the Secretary and risk-sharing HMOs. None of these facts, however, when analyzed in light of this Court's prior decisions, support the lower court's finding that Medicare HMOs were acting as a proxy for the Secretary.

First, the court of appeals stated that the government regulates HMOs' activities as they apply to Medicare beneficiaries, especially benefit coverage determinations. *Grijalva*, 152 F.3d at 1120. This Court has consistently held, however, that extensive regulation of an industry does not render private actions by members of that industry government action subject to constitutional restrictions. *Sullivan*, slip op., at 10; *Blum*, 457 U.S. at 1004; *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 350 (1974). If simple imposition of government regulations created government action, then virtually every action by an HMO would be classified as such. HMOs are regulated under federal and state law. Moreover, many healthcare plans provided by HMOs are provided through employer groups and are governed by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§1001, *et seq.* (1999). These provisions frequently impose mandates that include providing certain appeal rights to subscribers to protest any medical coverage

determinations made by an HMO. *See, e.g.*, ERISA, 29 U.S.C. §1133 (1999); *see also*, Md. Code Ann., Ins. Art §15-10A-02 (1997 & Supp. 1998). If each of these requirements transformed HMO coverage decisions into government action, then little of what HMOs do would escape the due process requirements of the Fifth or Fourteenth Amendment. As the Court made clear in *Sullivan*, such expansive applications of the government action doctrine are disfavored.

Second, the courts below relied on the fact that the Secretary issued regulations regarding internal appeal processes under the Medicare program to demonstrate joint participation. *Grijalva*, 152 F.3d at 1120. Yet, this is no different from the prior factor—there is a substantial regulatory framework governing Medicare. The Court has previously held that this type of regulatory framework, and the fact that participants must operate within that framework, does not convert otherwise private action into government action. *Blum*, 457 U.S. at 1000. Moreover, the internal appeal processes are common to HMOs and not unique to Medicare. In private contracts, HMOs often provide similar, if not identical, internal appeals processes. Accordingly, this fact indicates traditional private action, not action attributable to the sovereign.

Third, the courts below found that the Secretary has delegated medical coverage decisions to HMOs. *Grijalva*, 152 F.3d at 1120. The Secretary, however, could not delegate these decisions because they were never hers to make. The Medicare statute specifically prohibits the "exercise [of] any" governmental "supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. §1395. Given this prohibition, the independent determinations of medical coverage by HMOs participating in the Medicare program cannot fairly be attributed to the Secretary.

Moreover, in *Sullivan*, the Court rejected this precise argument as an overly simplistic approach to addressing government action.

> Such permission of a private choice cannot support a finding of state action. As we have said before, our cases will not tolerate 'the imposition of Fourteenth Amendment restraints on private action by the simple device of characterizing the State's inaction as authorization or encouragement.'

Sullivan, slip op., at 12 (quoting *Flagg Bros.*, 436 U.S. at 164-165). Neither Respondents nor the courts below have demonstrated that HMOs fail to exercise independent judgment when denying claims based on issues of medical appropriateness, necessity or coverage.

To be considered government action, these medical coverage decisions must be both traditionally and exclusively a government function. *Blum*, 461 U.S. at 1005; *Jackson*, 419 U.S. at 353; *see*, *Flagg Bros.*, 436 U.S. at 157-161. Such exclusive functions would include conducting elections, *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 624 (1991), exercising the power of eminent domain, *Jackson*, 419 U.S. at 352-354, or governing a city or a town, *Marsh v. Alabama*, 326 U.S. 501 (1946). Decisions as to the medical appropriateness of care are not a "traditional government function," giving rise to government action. *Edmonson*, 500 U.S. at 622.

To the contrary, HMOs, not the government, make determinations every day regarding the medical appropriateness and necessity of medical treatment. HMOs routinely make these decisions in commercial relationships as well as government-sponsored health benefits programs. As the Court pointed out in *Sullivan*, this function is a "traditionally private prerogative" that, no matter how it is characterized, does not constitute government action. *Sullivan*, slip op., at 15. Simply put, the "day-to-

day" determinations of healthcare benefits is not a function that is "traditionally the exclusive prerogative of the state." *Blum*, 457 U.S. at 1005 (citing *Jackson*, 419 U.S. at 353).

Fourth, the court of appeals found that HMOs' coverage decisions were government action based, in part, on the fact that the government "pays HMOs for each enrolled Medicare beneficiary . . ." *Grijalva*, 152 F.3d at 1120. Yet, the identity of the payor of benefits is not germane to the issue of whether or not risk-sharing HMOs under the Medicare program are government actors. As the Court affirmed in *Sullivan*, there are two prerequisites for determining when private action constitutes government action. The first factor is whether the right or privilege at issue is created by the government. *Sullivan*, slip op., at 8; *also see*, *Lugar*, 457 U.S. at 937. The fact that Medicare is federally funded may satisfy this factor. This funding, however, does not affect the second factor, whether the private party can be considered a "government actor." *Blum*, 457 U.S. at 1011. As the Court held in *Blum*, the funding of a program does not affect whether or not the actions of a private party are considered government acts. *Ibid.*

Finally, the court of appeals found that the fact that Medicare beneficiaries can appeal HMO service denials directly to the Secretary who "has the power to overturn the HMO's decision" was pertinent to the government action analysis. *Grijalva*, 152 F.3d at 1120. To the contrary, if the mere fact that private decisions by HMOs can ultimately be appealed to and overturned by some government authority, administrative body or court was attributable to the government, then almost all coverage decisions by HMOs constitute government action. Coverage decisions can almost always be appealed to various state administrative agencies, state courts, or federal

courts. Indeed, this Court did not find government action in the *Sullivan* case even though employees could appeal the workers' compensation insurance determinations to a workers' compensation administrative law judge for *de novo* review. *Sullivan*, slip op., at 5. Similarly, the availability of an appeal to the Secretary of an initial coverage determination by an HMO does not render the HMO's original determination government action.

In sum, the facts relied on by the court of appeals in its decision do not justify the conclusion that private determinations as to medical coverage by HMOs constitute government action. Rather, decisions regarding medical coverage have been traditionally private action. In fact, the very Medicare statute that the court of appeals relied on for finding government action specifically prohibits the Secretary from supervising or controlling such decisions.

II.

HMOs' PRIVATE ACTIONS, TO THE EXTENT THEY VIOLATE THE MEDICARE STATUTE AND REGULATIONS, DO NOT CONSTITUTE GOVERNMENT ACTION

The courts have recognized that a state or federal agency cannot be held liable for actions of a private party in violation of that agencies' regulations or authorizing statutes. *Starnes v. Capital Cities Media, Inc.*, 39 F.3d 1394, 1397 (7th Cir. 1994) (citing *Lugar*, 457 U.S. at 937) ("Misuse of state law is not, however, state action for the purposes of the Fourteenth Amendment."); *cf.*, *Flagg Bros.*, 436 U.S. at 166 (a state's refusal to act does not constitute state action under the Fourteenth Amendment). By its very definition, private actions taken in violation of statutory or regulatory mandates are not undertaken at the "coercive power" or through "significant encouragment" of state or federal agencies. *Blum*, 457 U.S. at 1004.

Yet, in essence, that is what Respondents alleged in their complaint below. Respondents complained that HMOs were not abiding by the Medicare statute and the Secretary's regulations in providing benefits, notice of denials and other procedural safeguards. According to the court of appeals, Respondents sought declaratory injunctive relief against the Secretary for failing "to enforce due process requirements," and "to monitor HMOs and ensure that HMOs provided Medicare covered benefits." *Grijalva*, 115 F.3d at 1117. The actions complained of by Respondent cannot, by definition, constitute government action subject to constitutional mandates of due process.[3] HMOs allegedly acting in violation of the statutory and regulatory mandates under the Medicare program can hardly be deemed as acting as a proxy for the Secretary.

II

PERMITTING THE COURT OF APPEALS' THEORY OF GOVERNMENT ACTION TO STAND WILL HAVE FAR-REACHING UNFAVORABLE IMPLICATIONS

If the court of appeals' holding in this case is permitted to stand, serious adverse consequences will result. The court of appeals' decision below is an expansive and unwarranted application of the government action doctrine. In addition, the injunction is nationwide resulting from a national class action. The variegated potential implications of the decisions below alone warrant close examination of the Petition in this case.

The court of appeals' decision discourages HMO participation in Medicare. Medicare+Choice plans contracted with the Secretary based on the understanding they were subject to the statutory and regulatory requirements of the Medicare program. The decisions below threaten to

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[3] The only exception to this is Respondents' complaint that the regulatory appeal process for denial of "emergency" benefits is not sufficiently expedited to afford beneficiaries due process.

scuttle the regulatory requirements developed by the Secretary and augment or replace those standards with others developed by the courts on an *ad hoc* basis pursuant to the government action doctrine. Current Medicare+Choice participants are left uncertain as to the regulatory framework in which they are operating. Prospective Medicare+Choice plans must decide whether to join the program in the face of an unsettled regulatory scheme that, according to the court of appeals' decision, can be changed by claims of due process violations by Medicare beneficiaries.

In addition to this uncertainty, each additional due process requirement imposed by the courts will create additional financial and administrative burdens on HMOs, further limiting the willingness of HMOs and other private organizations to participate in the Medicare+Choice program. At a minimum, these increased costs could result in decreased benefits to Medicare beneficiaries. A decrease in participation by HMOs in the Medicare+Choice program will reduce the choice of plans and potentially limit the benefits available to beneficiaries.

The remedies mandated by the district court will also adversely impact the Medicare program, beneficiaries and participating HMOs. The district court's injunction requires HMOs to give beneficiaries written notice whenever a coverage determination results in a service or referral requested by a healthcare provider or enrollee being denied, or an ongoing course of treatments being reduced or terminated. Pet. Br. at 7, Pet. App. at 60a. The injunction in place appears to require HMOs to provide notice of each reduction or termination of a health benefit, even if ordered by the beneficiary's healthcare provider because his or her condition has improved to the degree that the benefit is no longer

necessary. Requiring notice in such situations will only serve to confuse beneficiaries and burden HMOs.

The injunction may also require a similar notice if an HMO changes its Medicare benefits. HMOs currently provide services in addition to the standard benefits mandated under the Medicare Act. HMOs provide these services based upon a comparison of the Medicare rates to the costs of such benefits in the commercial market. An HMO may alter its benefits in any given year to reflect the commercial market realities. Under the injunction, it is unclear whether an HMO can effectuate a reduction or elimination of any benefit without a due process notice and hearing.

Equally alarming is the district court mandate prohibiting the Secretary from renewing contracts with HMOs that fail to comply the court's notice requirements. *Grijalva,* 946 F. Supp. at 760. As explained above, the notice requirements imposed by the district court are vague and flawed. HMOs may fail to comply with the notice provisions, not out of neglect or other wrongdoing, but rather because of misunderstandings as to the notice requirements. The draconian sanction of non-renewal of contracts imposed by the district court, if upheld, will create a serious disincentive for HMOs currently participating in the program as well as for those plans considering future participation in Medicare+Choice. Moreover, once a contract is not renewed, the HMO is precluded from participating in the Medicare Program for five years. 42 U.S.C. §1395w-27(c)(4).

The court of appeals' decision below will also undoubtedly become a launching pad for new litigation to challenge Medicare+Choice HMOs' actions in the courts. Providers will now argue that HMOs are acting as a proxy for the Secretary when they determine the providers with

whom they wish to contract. As such, providers will contend that they are all entitled to due process before HMOs can decide not to enter into a contract or renew a contract with the provider. Indeed, at least one Medicaid provider has already cited the decisions below for the proposition that a health plan contracting with a state Medicaid program is a government actor that must provide procedural due process before deciding not to renew a provider's contract. *Catanzano*, 103 F.3d at 227.

In sum, it is foreseeable that decisions other than coverage determinations, e.g., decisions about administrative policy, changes in benefit packages, exiting a service area or terminating provider contracts, could also implicate substantive or procedural due process rights under the lower courts' decisions. The outgrowth of those decisions may very well circumvent the balance of interests established under the BBA. Constitutionalizing the private relationship between providers and HMOs also disturbs an area traditionally defined by contract, and to some degree, by statute and regulation.

IV.
THE BALANCED BUDGET ACT OF 1997 MANDATES THE CASE BE VACATED AND REMANDED

In August 1997, Congress passed the BBA. This Act abolished risk-sharing HMOs in the Medicare Program as of January 1, 1999, and effectively repealed the statutory provision at issue in this case. The BBA, in addition to eliminating risk-sharing HMOs, established enhanced regulations governing the notice and appeal opportunities provided to beneficiaries by HMOs participating in the Medicare+Choice program. In short, the BBA and the regulations promulgated thereunder addressed the concerns raised by the courts below. As a result, the deci-

sions below must be remanded to address the notice and appeal issues under the new statutory and regulatory framework.

The BBA and the regulations promulgated thereunder, now require, *inter alia*, understandable written notices of decisions, 111 Stat. 293 (Section 1852(g)(1); 42 C.F.R. 422.568(d)); medical necessity decisions made by qualified medical personnel, 111 Stat. 293 (Section 1832(g)(2)(B); 42 C.F.R. 422.590(g)(2)(B)); and timely initial and reconsideration decisions. 111 Stat. 293-294 (Section 1852(g)(2) and (3); 42 C.F.R. 422.568(a), 422.572, 422.590(a)-(d)). These are precisely the issues that Respondents included in their complaint and that the district court addressed in its injunction.

These new provisions supersede the regulatory scheme that existed for risk-sharing HMOs and therefore eradicate the need for injunctive relief in this case. As this Court and the Petitioner have rightly stated, the law has " 'been sufficiently altered' pending appeal 'so as to present a substantially different controversy than the one the [lower courts] originally decided.' " Pet. Br. at 35 (quoting *Northeastern Fla. Chapter of the Associated Gen. Contractors v. City of Jacksonville*, 508 U.S. 656, 662 n.3 (1993); *id.* at 670-671 (O'Connor, J., dissenting)). The BBA's abolishment of the statutory basis for the district court and court of appeals' decisions, coupled with this Court's decision in *Sullivan*, mandate that the judgment of the court of appeals be vacated and remanded to the district court.

CONCLUSION

The courts below improperly held that coverage determinations made by Medicare HMOs constitute government action. Consistent with the *Sullivan* decision, neither the Respondents nor the court of appeals can transform these private decisions into federal action. Accordingly, the Court should grant the Petition for Writ of Certiorari, vacate the judgment of the court of appeals, direct the court of appeals to vacate the judgment of the district court and remand the case to the district court for further review in light of the *Sullivan* decision, the BBA and its implementing regulations.

Respectfully submitted,

JEFFREY W. KING
(Counsel of Record)
CHRISTOPHER FLYNN
KING, PAGANO & HARRISON
1730 Pennsylvania Ave., N.W.
Suite 900
Washington, D.C. 20006
(202) 371-6800
Counsel for Amicus Curiae American Association of Health Plans.

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